

## **MEDICAL BOARD OF CALIFORNIA**

### **INITIAL STATEMENT OF REASONS**

Hearing Date: November 5, 2010

Subject Matter of Proposed Regulations: Polysomnography Program

Sections affected: Adopt Sections 1378.1, 1378.3, 1378.5, 1378.7, 1378.9, 1378.11, 1378.13, 1378.15, 1378.17, 1378.19, 1378.25, 1378.27, 1378.29, and 1378.35, in Article 1, of Chapter 3.5, Division 13, of Title 16.

#### Introduction

Senate Bill (SB) 132, Denham, (Statutes of 2009) adding Chapter 7.8 to Division 2 of the Business and Professions Code, took effect as an urgency measure on October 23, 2009. SB 132 requires the Medical Board of California (Board or board) to adopt regulations within one year of the effective date of this act relative to the qualifications for certified polysomnographic technologists, including requiring those technologists to: be credentialed by a board-approved national accrediting agency; have graduated from a board-approved educational program; and, have passed a board-approved national certifying examination (with a specified exception for that examination requirement for a three-year period).

Additionally, SB 132 prohibits a person from using the title “certified polysomnographic technologist” or engaging in the practice of polysomnography unless: he or she undergoes a Department of Justice background check, as specified; is registered as a certified polysomnographic technologist; is supervised and directed by a licensed physician and surgeon; and meets other requirements. SB 132 also defines polysomnography to mean the treatment, management, diagnostic testing, control, education, and care of patients with sleep and wake disorders. SB 132 further requires the board to adopt regulations related to the employment of polysomnographic technologists, technicians and trainees.

#### Specific Purpose of each adoption:

1. Section 1378.1 (Definitions) This section defines terms mentioned throughout the proposed regulations.

#### Factual Basis/Rationale:

After extensive research, contact with other State Medical Boards and after the Board’s interested parties meeting, the Board has determined that the following accredited programs are acceptable to accredit educational programs of this registrant category, because the standards in place support the Board’s mission of public protection and are sufficient to reflect the services to be provided by the registrant.

### Polysomnographic Educational Programs:

- The Commission on Accreditation of Allied Health Education Programs (CAAHEP) is the largest programmatic accreditor in the health science field. CAAHEP relies on its committees to develop standards and qualifications necessary for accreditation. The standards for polysomnography technology educational programs include core curricula that address the safe and effective care and monitoring of the patient and the education must be offered in a setting with sufficient educational and oversight resources.
- The Commission on Accreditation for Respiratory Care (CoARC) is the sole nationally recognized authority for the accreditation of first professional degree programs in respiratory care. CoARC's accreditation standards include requirements for curricula that address the safe and effective treatment and monitoring of the patient, and the education must be offered in a setting with sufficient educational and oversight resources.

### Sleep Technologist Program

- The American Academy of Sleep Medicine (AASM) is the only entity that sets standards in sleep medicine health care, education and research. The AASM's A-STEP educational programs consists of an 80-hour course on sleep and sleep related issues and patient care, and that course is followed by a fourteen module self-study session undertaken while an individual receives on-the-job polysomnographic training.

After extensive research, contact with other State Medical Boards and after the Board's interested parties meeting the Board has determined that the following program is acceptable to assess the professional competence of this registrant category because the standards in place support the Board's mission of public protection and are sufficient to reflect the services to be provided by the registrant.

### Examination and Credentials

- The Board of Registered Polysomnographic Technologists (BRPT) assesses the professional competence of practitioners performing polysomnography and associated therapeutic interventions. BRPT's credentialing program is accredited by the National Commission of Certifying Agencies (NCCA). Currently, the BRPT is the only organization that certifies Polysomnographic Technologists and Technicians.

After extensive research, contact with other State Medical Boards and after the Board's interested parties meeting the Board has determined that the following program is acceptable to assess the professional competence of this registrant category. The requirements to sit for the BRPT certification examination include direct polysomnography patient care experience or graduation from an approved polysomnography educational program.

Supervising Physician and Surgeon. This definition was used to ensure that the physician and surgeon(s) supervising polysomnographic registrants have the necessary expertise and knowledge to properly monitor and direct the actions of the registrants.

“Board” means the Medical Board of California. This definition is used to promote readability and brevity.

“Code” means the Business and Professions Code. This definition is used to promote readability and brevity.

2 . Section 1378.3 (Delegation of Functions) This section delegates the Executive Director as the responsible party for administering all functions of this program except for those reserved to the agency (here, the Board) itself.

Factual Basis/Rationale:

Per existing law, the Executive Director of the Board is charged with overseeing the day to day activities of Board operations. This section would authorize the Executive Director to carry out administrative tasks associated with the implementation and operation of the polysomnographic registration program. This section helps to provide smooth and efficient functioning and administration of the polysomnography registration program.

3 . Section 1378.5 (Applications) This section is necessary to establish a standard and uniform application to be used for all registration categories. The applicant will provide the contact information on the application, this is necessary in order to interact with the applicant. Additionally, the remaining provisions establish the requirements needed for registration.

Factual Basis/Rationale:

Per SB 132, polysomnography registrants must complete an application to ensure they meet the necessary requirements for registration. The application requires the applicant to provide: name, social security number, contact information, educational information, current and/or previous examination and certification information, current and/or previous registration/licensure information, denials and conviction of crimes. Also, the application, through the work experience verification form, provides the Board with the necessary information regarding the applicant's previous experience in providing polysomnographic services under the supervision of a licensed physician. The application also requires a current photograph and requires that the application be notarized. The application is attached.

4. Section 1378.7 (Abandonment of Application) This section requires an applicant for registration to complete the requirements for registration within one year of the date the application is filed. If an application is submitted after a previous application was deemed abandoned, the Board will treat that application as a new application, meaning that the applicant will have to include the applicable fees.

Factual Basis/Rationale:

The Board currently licenses physicians and surgeons and it is the Board's experience that dormant licensing applications consume resources, as these applications must be retained in both electronic and paper formats. In addition, Board staff is obligated to re-review these applications periodically to determine if the applicant's status has changed and then contact the applicants to ask if they intend to pursue or complete registration in the near future. Without

setting a date by which the process must be completed, an applicant can call the Board and request that the file be kept open without making any progress toward actually satisfying the registration requirements. The one year period gives the applicant ample time to provide the documents necessary to complete the registration process. This one year period has been the Board's existing policy for many years.

5. Section 1378.9 (Examination) This section specifies the certifying examination approved by the Board and how, in lieu of the examination, the applicant can apply for registration prior to October 23, 2012.

Factual Basis/Rationale:

Applicants will be required to take a certifying examination offered by the Board of Registered Polysomnographic Technologists (BRPT), the only entity offering such an exam for certification as a Registered Polysomnographic Technologist or Technician. The BRPT assesses the professional competence of practitioners performing polysomnography and associated therapeutic interventions. The BRPT credentialing program is accredited by the National Commission of Certifying Agencies (NCCA). Currently the BRPT is the only organization that certifies Polysomnographic Technologists and Technicians.

However, as specified in SB 132, an applicant who applies for registration as a technologist before October 23, 2012, can substitute five years of polysomnographic experience in lieu of successfully completing the examination. To ensure an applicant has five years of safe polysomnographic practice, he or she must submit declarations from a supervising physician or letters of good standing from another state in which the applicant is registered or licensed.

6. Section 1378.11 (Registration Requirements) This section specifies the requirements that must be met to register as a polysomnographic technologist, technician and trainee.

Factual Basis/Rationale:

The Board has reviewed the laws of two other State Medical Boards (Maryland and New Mexico) who are currently licensing/registering polysomnographic technologists, technician and trainees. The Medical Board of California has imposed similar requirements sufficient to protect California consumers and promote the safe practice of polysomnography.

The basic level of registration, the trainee, requires that the applicant possess a Basic Life Support certification (BLS) issued by the American Heart Association. This item was brought up at an interested parties meeting and the Board was agreeable to this suggestion and believes it is necessary to ensure public protection as the trainee would be able to administer cardio pulmonary resuscitation to a patient if the circumstances warrant. Additionally, a trainee must have a high school diploma (or equivalent) and six months of supervised patient care or be currently enrolled in an approved polysomnographic education program to meet the requirements for registration in California. Finally, a trainee applicant must not be subject to denial for criminal conviction or other acts involving incompetence, negligence, fraud, or other misconduct. This requirement is essential for public protection.

Polysomnographic technicians shall meet the above requirements relating to the BLS certificate

and not be subject to denial for misconduct and have requirements for more stringent educational and experience. These requirements are more comprehensive because the scope of practice is greater for technicians. Technologist applicants must comply with the registration requirements in SB 132 and possess the BLS certificate.

7. Section 1378.13 (Employment and Supervision of Registrants) This section defines who may supervise registrants and specifies the number of registrants a physician and surgeon or other licensed health care professional may supervise. This section also specifies the availability of a supervising physician and surgeon and establishes the requirements for a technologist if he/she supervises other polysomnographic registrants. Finally, this section provides that a supervising physician and surgeon is not relieved from the responsibility of the patient's welfare by the delegation of procedures to a polysomnographic registrant or other licensed health care professional.

Factual Basis/Rationale:

During the Polysomnography interested parties meeting, the physician to technologist ratio was discussed. Members of the audience indicated that the industry standard is one technologist for every two patients. For a 16 bed facility, this would require eight technologists to be onsite. One physician would be on call and the technologists would report to the one physician. The American Academy of Sleep Medicine supports this ratio. The Board agreed that the ratio of one supervising physician to every eight technologists is appropriate and a necessary standard for consumer protection. This is the same ratio for a technologist to supervise trainees or technicians. The Board believes that the eight to one ratio will allow for the efficient provision of services while maintaining an adequate level of consumer protection. The last item – the continued responsibility of the physician and surgeon – serves to reinforce the concept that polysomnographic services must be provided under the supervision and direction of a licensed physician and surgeon.

8. Section 1378.15 (Scope of Services – Polysomnographic Trainee) This section is necessary to define the scope of practice for polysomnographic trainees.

Factual Basis/Rationale:

The American Academy of Sleep Medicine (AASM) sets standards in sleep medicine health care, education and research. Using guidelines supported by the AASM, it was determined that a polysomnographic trainee under the direct supervision of a physician and surgeon, technologist or other licensed health care provider may provide basic supportive services as part of the trainee's educational program. As the trainee has limited expertise and education, public protection dictates that the scope of practice is not overly broad.

9. Section 1378.17 (Scope of Services – Polysomnographic Technician) This section is necessary to define the scope of practice for polysomnographic technicians.

Factual Basis/Rationale:

The American Academy of Sleep Medicine (AASM) sets standards in sleep medicine health care, education and research. Using guidelines supported by the AASM, it was determined that

a polysomnographic technician may provide services under general supervision and may implement appropriate interventions necessary for patient safety. As a technician has more experience and education, the scope of services is expanded.

10. Section 1378.19 (Notice to Consumers) This section requires a notice be posted or provided to the consumer. This notice informs the consumer that the practice of polysomnography is regulated by the Medical Board of California.

Factual Basis/Rationale:

By law, public protection is the highest priority of the Board, and the public protection is enhanced when patients and other interested parties are made aware of the Board's existence at a time close to when polysomnographic services are provided.

Public protection is the highest priority of the Board whenever it exercises its regulatory authority. The Board has recently implemented a similar notification requirement for consumers regarding physicians and surgeons.

This proposed regulation also comports with the provisions of section 138 of the Business and Professions Code, which requires constituent boards within the Department of Consumer Affairs to promulgate regulations regarding notice that a practitioner is licensed by the state. The Medical Board is a constituent board of the Department.

11. Section 1378.25 (Substantial Relationship Criteria) This section establishes that the conviction of specified crimes shall serve as a basis for the denial, revocation, or suspension of a registration and defines these crimes as substantially related to the practice of polysomnography.

Factual Basis/Rationale:

Section 480 of the Business and Professions Code provide that a board with the Department of Consumer Affairs may deny, revoke, or suspend a license or registration if the applicant or licensee has been convicted of a crime substantially related to the licensed activity. This regulation defines those crimes. Prudent policy dictates that the public may not be served best by allowing a person convicted of a crime of physical violence, dishonesty, or sexual misconduct to provide these services, especially when the patient may be in a vulnerable situation or a remote location.

12. Section 1378.27 (Criteria for Rehabilitation for Denial and Reinstatement) This section establishes the criteria by which the Board evaluates the reinstatement of a revoked registration or considers the denial of a registration.

Factual Basis/Rationale:

The Board recognizes that applicants and licensees may have committed offenses in the past. This section sets the criteria for the Board to determine if issuing a registration or reinstating a registration is inconsistent with or contrary to the public interest. The standard of evaluating the reinstatement of a revoked registration or the denial of a registration is set forth in Title 16 of the

California Code of Regulations. This criteria will allow the Board to determine if the individual has been sufficiently rehabilitated such that he or she may provide polysomnographic services safely.

13. Section 1378.29 (Rehabilitation Criteria for Suspensions and Revocations) This section establishes the process when the Board is considering the suspension or revocation of a registration based upon the conviction of a crime.

**Factual Basis/Rationale:**

The Board recognizes that applicants and licensees may have committed offenses in the past. This section sets the criteria for the Board to determine if issuing a registration or reinstating a registration is inconsistent with or contrary to public interest. The standard of considering the suspension or revocation of a registration is set forth in Title 16 of the California Code of Regulations. This criteria will allow the Board to determine if the individual has been sufficiently rehabilitated such that he or she may provide polysomnographic services safely.

14. Section 1378.35 (Fees) This section establishes different types of fees for this registration category.

**Factual Basis/Rationale:**

Since this is a new registration category for the Board, a fund has to be established to administer this registration program. The \$100.00 application fee will be used to defray the cost of time it will take the office staff to process the application for completeness and ensure the applicant has submitted all the documents needed to qualify the applicant for registration in California. The \$100.00 registration fee will be used to defray the cost of registration cards and to defray that cost of office staff to process the registration. The \$175.00 renewal fee will ensure the continued administration of the polysomnography registration program. The maximum fees were imposed, and adhere to the guidelines of SB 132, to ensure this new registration program has funds to administer the program as well as funds to develop the Applicant Tracking System, the Consumer Affairs System, enforce the law and to ensure the program has a reserve for economic uncertainties.

**Underlying Data:**

Technical, theoretical or empirical studies or reports relied upon (if any): Information from the American Academy of Sleep Medicine (AASM); Commission on Accreditation of Allied Health Education Programs (CAAHEP); Commission on Accreditation for Respiratory Care (CoARC); Board of Registered Polysomnographic Technologists (BRPT); California Sleep Society; New Mexico Medical Board; Louisiana State Medical Board; Maryland State Medical Board; and the June 16, 2010, interested parties meeting.

**Business Impact:**

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the following facts or evidence/documents/testimony:

The regulation impacts those persons applying to the Medical Board for polysomnography technologist, technician and trainee registration as well as those licensed physicians and surgeons who elect to supervise them.

The proposed regulation may create jobs in California as it prescribes a pathway for persons to become licensed in a health care field. Supervising physicians may hire registrants to provide these services.

#### Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

#### Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

Set forth below are the alternatives that were considered and the reasons each alternative was rejected:

- No alternative was considered as the law requires polysomnographic technologist, polysomnographic technicians and polysomnographic trainees be regulated by the State of California.